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09/902,287

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Michael Conor Minogue

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09/22/2004

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EXAMINER

MULLEN, KRISTEN DROESCH

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/902,287

Applicant(s)

MINOGUE ET AL.

Examiner

Kristen Mullen (formerly
Droesch)

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7-30-04 (after final amendment).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-11 and 14-71 is/are rejected.
- 7) ☒ Claim(s) 12 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The finality of the rejection of the last Office action is withdrawn.

Claim Objections

2. Claim 59 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 64, 69, and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 64 recites the limitation "the interval between pulses of each pulsed interval" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 69 recites the limitation "the duration of each pulsed signal" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 71 recites the limitation "the magnitude of each pulse of each pulsed signal" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3-11, 14-28, 32-39, 44-45, and 48-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Russek (4,381,012).

Regarding claim 1, Russek shows a device including attachment means (120) for extending around the torso of a subject; a main locating means (51-54) for locating a central electrode (50) substantially about the umbilicus of the subject; and two secondary locating means (55, 56) provided on the attachment means disposed on opposite sides of the main locating means for locating two corresponding side electrodes of the at least three electrodes, a first of the two side electrodes (placed at 55 or 56) spaced apart from the central electrode (placed at 51-54) in a general direction of towards the left mid-axillary line or the subject and a second of the two side electrodes (placed at 55 or 56) spaced apart from the central electrode (placed at 51-54) in a general direction of towards the right mid-axillary line or the subject (Fig 7).

Regarding claims 3-5, Russek shows the secondary locating means (55, 56) are disposed on the attachment means *for* locating the respective side electrodes toward the midpoint of the corresponding mid-axillary line between the rib cage and the corresponding iliac crest, adjacent the corresponding mid-axillary line, and adjacent the midpoint of the corresponding mid-axillary line between the rib cage and the corresponding iliac crest (Fig 7).

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With respect to claims 6-7, Russek shows the main locating means (51-54) is disposed on the attachment means *for* locating the central electrode on the umbilicus and extending completely around the umbilicus (Fig. 7).

Regarding claims 8-10, Russek shows a reference means (4) *for* locating the attachment means on the torso relative an anatomic reference, circumferentially around the torso and vertically along the torso (Fig. 7).

With respect to claim 11, Russek shows the main locating means (51-54) act as a reference means *for* locating the attachment means relative to the umbilicus (Fig. 7). The examiner points out that one can see and feel the locating means on the attachment means.

The functional language and statements of intended use (such as “for”) have been carefully considered but are not considered to impart any further structural limitations over the prior art.

With respect to claims 14-15, Russek further shows the attachment means comprises a resilient material being of greater stretchability than that of other materials of the attachment means (Col. 3, lines 9-50).

Regarding claims 16-17, Russek further shows the main electrically conductive contact means (50) is provided on the attachment means corresponding to the main locating means and located within and adjacent to the main locating means (54) (Figs. 7-8).

With respect to claims 18- 20, Russek further shows two secondary electrically conductive contact means (50) on the attachment means, and each secondary contact means (50) is located adjacent the secondary locating means (55, 56) (Col. 5, lines 1-25).

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With respect to claims 21-22, Russek further shows each main and secondary locating means (51-56) is provided as a visually perceptive locating means and formed as a corresponding locating mark on the attachment means (Fig. 7).

Regarding claim 23, Russek shows each locating means (51-56) is adapted for locating a patch type electrode (50) (Fig. 7).

With respect to claims 24-25, Russek shows at least three patch electrodes (50) are formed as a removable part of the device (Col. 5, lines 1-25; Fig. 7).

Regarding claim 26, Russek shows each side electrode is sized to cover at least a portion of the corresponding lower thoracic nerves and the corresponding second lumbar nerves. The side electrodes of Russek, if applied to the abdomen rather than the back, are of sufficient size to cover at least a portion of the corresponding lower thoracic nerves and the corresponding second lumbar nerves.

With respect to claim 27, Russek shows each central electrode (50, 53, 54) is sized to extend substantially across the rectus abdominus muscle (Fig. 9; Col. 10, line 40-Col. 11, line 17). The central electrode of Russek, if applied to the abdomen rather than the back, is of sufficient size to extend *substantially* across the rectus abdominus muscle.

Regarding claim 28, Russek further shows the area of contact of each side electrode (electrodes 50 corresponding to 55, 56) does not exceed the area of contact of the central electrode (electrodes 50, corresponding to 51, 52, 53, 54) (Figs. 7-8).

With respect to/regarding claims 32, 37, Russek further shows a receiving means (83) provided in the attachment means for receiving a signal generating means (82) and the receiving means is a releasable receiving means for releasably receiving the signal generating means (Col. 5, lines 62-68).

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Regarding claims 33-36, Russek further shows main and secondary electrical connecting means (8-13) located in the attachment means and extending between the receiving means and the signal generating means (TENS) and the main contact means and extending between the receiving means and the secondary contact means (Figs. 1, 3, 4-5, 7).

With respect to claim 38-39, Russek further shows the attachment means comprises a belt (Figs. 1, 3, 7, 9, 12, 13) and a securing means (2, 3).

Regarding claims 40-43, Russek further shows main fastening means comprising stud fasteners (51-54, 61-64) provided corresponding to the main locating means and secondary fastening means comprising stud fasteners (55-56, 65-66) for fastening the respective side electrodes to the attachment means adjacent the secondary locating means (Figs. 7-11, 18; Col. 5, lines 26-54).

Regarding claim 44, Russek further shows each stud fastener comprises a female (51-56, 61-66) and male part (57, 66') (Figs. 9-10, 18)

With respect to claim 45, Russek further shows each stud fastener is electrically conductive (Col. 5, lines 26-54).

Regarding claims 48-49, Russek shows each stud fastener comprises a first part (57) for attaching to a corresponding electrode and a second part (51-56, 61-66, 66') for attaching to the attachment means wherein the first and second parts engage each other with electrically conductive engagement (Figs. 7-11, 18).

7. Claims 52-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Piunti (5,724,996).

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With respect to claims 52, and 59, Piunti shows providing at least three electrodes, one electrode being a central electrode and the other two electrodes being side electrodes, passing at least one pulsed signal subcutaneously through the subject between the at least three electrodes (Figs. 2-3, 8; Col. 3, lines 5-25; Col. 4, lines 8-13).

Regarding claim 53-58, the statements of intended use have been carefully considered, but are not deemed to place any further restrictions on the method. The location of the various electrodes on the subject is deemed to be intended use since the steps of placing the various electrodes in the various locations has not been recited.

With respect to claim 60, Hurtado further shows the at least one pulsed signal is applied simultaneously to each of the side electrodes (Claims 1, 4).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Russek (4,381,012). Russek discloses the claimed invention except for each set of secondary locating means comprising three secondary locating means. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify each set of secondary locating means with two secondary locating means as taught by Russek with each set of secondary locating means having three secondary locating means, since applicant has not disclosed that this third locating means provides any criticality and /or unexpected results and it appears that the invention would perform

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equally well with any number of secondary locating means in the set of secondary locating means such as the two secondary locating means as taught by Russek for locating electrodes on the belt.

10. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Russek (4,381,012). Russek discloses the claimed invention except for the specific size of the each side electrode. It would have been an obvious matter of design choice to form the side electrode having a width of 50 mm to 150 mm since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 UPSQ 237 (CCPA 1955).

11. Claims 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Russek (4,381,012) in view of Linder (5,190,036). Russek shows all but the electrodes having a gel type coating provided on a side of each electrode facing away from the attachment means. Attention is directed to Linder, which shows electrodes with an electrically conductive gel-type coating provided on a side of each electrode facing away from the attachment means in order for the electrode to make electrical contact with the skin (Col. 3, lines 24-33). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Russek to include a conductive gel-type coating provided on a side of each electrode facing away from the attachment means as Linder teaches in order to make electrical contact with the skin.

12. Claims 46-47, and 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Russek (4,381,012) as applied to claims 44 and 48 above. Russek

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discloses the claimed invention except for showing the exposed surface of the portions of each stud fastener attached to the attachment means is of electrically insulating material provided by an electrically insulated coating. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the exposed portions of the stud fasteners as taught by Russek with insulating coatings in order to protect a user who may come into contact with the exposed portions of the stud fasteners from electrical shock.

13. Claims 61-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piunti (5,724,996). Piunti discloses the claimed invention except for each pulsed signal comprising a plurality of pulses at intervals in the range of 5 msec to 1000msec, 20 msec to 40 msec, and approximately 30 msec \pm 20%; and adjustable interval; each pulsed signal comprises pulses of duration in the range of 10 μ sec to 200000 μ sec, 50 μ sec to 1000 μ sec, 100 μ sec to 500 μ sec, approximately 300 μ sec \pm 20%; and adjustable duration; and each pulsed signal comprises a plurality of pulses of magnitude in the range of 0 mA to 100 mA and adjustable magnitude. It would have been an obvious design choice to one with ordinary skill in the art at the time of the invention to apply pulses comprising a plurality of pulses at intervals in the range of 5 msec to 1000msec, 20 msec to 40 msec, and approximately 30 msec \pm 20%; and adjustable interval; pulses of duration in the range of 10 μ sec to 200000 μ sec, 50 μ sec to 1000 μ sec, 100 μ sec to 500 μ sec, approximately 300 μ sec \pm 20%; and adjustable duration; and each pulsed signal comprising a plurality of pulses of magnitude in the range of 0 mA to 100 mA and adjustable magnitude, since applicant has not disclosed that these particular pulse parameters provide any criticality and /or unexpected results and it appears that the

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invention would perform equally well with any pulses such as the pulses taught by Piunti for improving the muscle tone of the abdomen.

Allowable Subject Matter

14. Claims 12-13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art of record fails to teach or suggest a device comprising attachment means for extending around the torso of the subject, a main locating means provided on the attachment means for locating a central electrode of the at least three electrodes substantially about the umbilicus of the subject; and two secondary locating means provided on the attachment means disposed on respective opposite sides of the main locating means for locating two corresponding side electrodes of the at least three electrodes, a first of the two side electrodes spaced apart from the central electrode and a second of the two side electrodes spaced apart from the central electrode all in combination with two sets of at least two secondary locating means disposed on the respective opposite sides of the main locating means.

Response to Arguments

15. Applicant's arguments with respect to claims 1, 3-11, and 14-71 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen (formerly Droesch) whose telephone number is 703-605-1185. The examiner can normally be reached on 10:30 am-6:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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